Meeting Minutes
Generic Drug Trades/FDA
Pediatric Exclusivity Provisions of the FDA Modernization Act

February 20, 1998

External Participants:
Gary Yingling, NPA
Leon Shargel, NAPM
Alice Till (via telephone), GPIA

FDA Participants:
Leanne Cusumano, Regulatory Policy Staff, CDER
Rosemary Roberts, M.D., Pediatric Subcommittee, CDER
Kathy Robie-Suh, Office of Review Management, CDER
Elizabeth Dickinson, Office of the Chief Counsel, FDA
Murray Lumpkin, M.D., Deputy Director, CDER
Cecelia Parise, Office of Generic Drugs, CDER
Jerry Phillips, Office of Generic Drugs, CDER
Gordon Johnston, Office of Generic Drugs, CDER
Doug Sporn, Office of Generic Drugs, CDER
Dale Connor, Office of Generic Drugs, CDER
Khyati Roberts, Executive Operations Staff, CDER

Type of Meeting: Information gathering meeting.
Meeting Chair: Murray Lumpkin
Meeting Recorder: Khyati Roberts

Meeting Objectives and Discussion: This meeting was scheduled to discuss the pediatric exclusivity provisions of the FDA Modernization Act (FDAMA). The goal was to hear the generic drug trade associations' perspective on some specific topics. The generic drug trade associations views follow FDA's questions.

What is meant by "may produce a health benefit" as used in Section 111(b)?

- The way in which this term is defined will define the impact on the generics.

- The list should be established using good scientific clinical criteria, e.g, nature of the indication, prevalence of use, need for alternatives, feasibility of doing studies. If a question arises about placing a drug on the list, it should be left off the list. The criteria used to place drugs on the list should be narrowly defined.

- The trade organizations also requested that the criteria to be used be published in draft prior to publication of the draft list. FDA noted that due to the time constraints, this may not be possible.

- Pediatric specialists should be used to help determine the list.

- FDA recommended generic drug industry track the impact the exclusivity provisions have on their industry because this is one of the issues upon which the Secretary must report.

- FDA noted that the list is not intended in any way to impact on pharmacy practice.

- If the list is broad, products that currently have no exclusivity or patent protection may be forced off the market by those products that are developed for use in pediatrics with patent or exclusivity protection for the same indications.

What should the "written request," as used in Section 111(a) and (c), contain? What should the format of the "written agreement," as used in Section 111(d)(1), be?

- The written request should be made so that the agency gets the quality of studies it needs to make a labeling change, e.g., size of study and exact pediatric population.

- The request should include the time frame for completion of studies.

When is a study considered completed?

- A study is considered completed when the agency has the data it needs to support the labeling change.

Attachment: GPIA Comments

Khyati Roberts
Meeting Recorder

Murray Lumpkin,
Chair

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February 17, 1998